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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,412	09/25/2007	Anna Helgadottir	30847/40792A	8479

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EXAMINER	
WOODWARD, CHERIE MICHELLE	
ART UNIT	**PAPER NUMBER**
1647	
MAIL DATE	**DELIVERY MODE**
05/12/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,412	HELGADOTTIR ET AL.	
	Examiner	Art Unit	
	CHERIE M. WOODWARD	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-4,7,11-14,18,23,24,26-34,37,38,43,45-47,52-55,59,62,64-67,74-78,82,83, and 85-95* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1-4,7,11-14,18,23,24,26-34,37,38,43,45-47,52-55,59,62,64-67,74-78,82,83 and 85-95.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4, 7, 11-14, 18, 23, 24, 26-29, and 85-87, drawn to a method for prophylaxis therapy for myocardial infarction comprising administering a therapeutic agent that inhibits FLAP activity.

Group II, claim(s) 30-34 and 88-90, drawn to a method for prophylaxis therapy for myocardial infarction comprising selecting a patient with a specific haplotype and administering a therapeutic agent that inhibits leukotrine synthesis.

Group III, claim(s) 37, 38, 43, and 45, drawn to a method for prophylaxis therapy for myocardial infarction comprising analyzing nucleic acids in a subject for specific FLAP haplotypes.

Group IV, claim(s) 46, drawn to a method for prophylaxis therapy for myocardial infarction comprising administering a therapeutic agent that inhibits leukotrine synthesis in a subject in need of prophylaxis for myocardial infarction.

.Group V, claim(s) 47 and 52, drawn to a method for screening a human subject for risk of developing myocardial infarction.

Group VI, claim(s) 53, drawn to a method of decreasing risk of a subsequent myocardial infarction in an individual who has had at least one myocardial infarction.

Group VII, claim(s) 54, drawn to a method of screening a human subject for susceptibility for myocardial infarction comprising analyzing nucleic acids of the subject for specific FLAP haplotypes.

Group VIII, claim(s) 55, 59, 62, and 64-67, drawn to a composition comprising a leukotrine synthesis inhibitor and a statin.

Group IX, claim(s) 74-76, drawn to a method of reducing C reactive protein in a human subject comprising administering a composition comprising a leukotrine synthesis inhibitor and a statin.

Group X, claim(s) 77, drawn to a method of reducing C reactive protein in a human subject comprising administering a composition comprising a leukotrine synthesis antagonist.

Group XI, claim(s) 78, 82, and 83, drawn to a method of reducing C reactive protein in a human subject comprising administering a composition comprising a leukotrine synthesis inhibitor and a statin and monitoring and modifying the amount or frequency of administration.

Group XII, claim(s) 91-93, drawn to a method of assessing susceptibility to myocardial infarction or stroke in a subject..

Group XIII, claim(s) 94 and 95, drawn to a method for prophylaxis therapy for myocardial infarction comprising selecting a human subject having multiple specific FLAP haplotypes and administering a therapeutic agent that inhibits leukotrine synthesis.

2. The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Claim 55 (the first product claim) is anticipated by Harlan et al., WO 2000/048626 (24 August 2000). Harlan et al., teach compositions comprising statins and leukotrine synthesis inhibitor, including an inhibitor of 5-LO (p. 10, lines 5-10; p. 18, lines 32-33 to p. 19, lines 1-2; p. 31, lines 9-14). Because claim 55 is anticipated by Harlan et al., the remaining claims lack the same or corresponding special technical feature and as such, lack unity. The expression "special technical features" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. The requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

3. This application contains claims directed to more than one alternative embodiments of the generic invention. These alternative embodiments are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The alternative embodiments are as follows:

a. A myocardial therapeutic agent (claims 1, 30, 37, 45, 46, 52, 53, and 94).

b. A specific inhibitor (or antagonist) of FLAP or 5-LO (claims 1, 43, 53, and 94).

c. One additional marker (claim 2).

d. One inflammatory marker (claim 13).

e. A leukotrine or leukotrine metabolite (claim 18).

f. A treatment type (claim 23).

g. A FLAP genotype or haplotype (claim 23).

h. A FLAP polymorphism (claim 24).

i. A Flap haplotype marker (claims 26, 37, and 54).

j. A treatment type (claim 37).

k. A calcium ionophore (claim 47).

l. A leukotrine synthesis inhibitor (claims 55, 65, and 74).

m. A statin (claims 55, 64, 74, and 77).

n. A FLAP inhibitor (claim 59).

o. Identify with specificity a prodrug, BAY-X-1005, or a pharmaceutically acceptable salt (claim 60).

p. MI, ACS, stroke, or PAOD (claim 75).

q. A specific composition comprising a statin (claim 78).

r. A specific composition comprising a leukotrine synthesis inhibitor (claim 78).

s. MI or stroke (claim 91)

t. One assay method from (a)-(d) in claim 93.

In order to be fully responsive, Applicant must elect one alternative embodiment from (a)-(t) above with particularity, corresponding with the claims from the elected group.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim. Currently, the following claim(s) are generic: 1, 30, and 55

REQUIREMENT FOR UNITY OF INVENTION

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

WHEN CLAIMS ARE DIRECTED TO MULTIPLE CATEGORIES OF INVENTIONS

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERIE M. WOODWARD whose telephone number is (571)272-3329. The examiner can normally be reached on Monday - Friday 9:30am-6:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cherie M. Woodward/
Primary Examiner, Art Unit 1647